

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Larsen, *et al.*

Serial No.:

Filed: herewith

For: Novel P-Selectin Ligand Protein

Attorney Docket No.: GFN-5213CP6CN

Group Art Unit:

Examiner:

Commissioner for Patents
Washington, D.C. 20231

CERTIFICATION UNDER 37 CFR 1.10

Date of Deposit: August 21, 2001

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I hereby certify that this 37 CFR 1.53(d) request and the documents referred to therein as enclosed are being deposited with the United States Postal Service on the date indicated above in an envelope as "Express Mail Post Office to Addressee" service under 37 CFR 1.10 and addressed to the Commissioner for Patents, Washington, D.C. 20231.

NELSON BARROS

Name of Person Mailing Paper

Nelson Barros

Signature of Person Mailing Paper

PRELIMINARY AMENDMENT

Dear Sir:

Prior to examination, please amend this application as follows:

In the Specification:

Please delete the first paragraph on page 1 and insert the following paragraph:

--This application is a continuation application of U.S. Serial No. 08/713,556, filed on August 30, 1996, Pending, which in turn is a continuation-in-part of U.S. Serial No. 08/428,734, filed April 25, 1995, issued as U.S. Patent No. 5,843,707, which was a continuation-in-part of copending application U.S. Serial No. 08/316,305, filed September

30, 1994, now abandoned, which was a continuation-in-part of copending application U.S. Serial No. 08/235,398, filed April 28, 1994, now abandoned, which was a continuation-in-part of copending application U.S. Serial No. 08/112,608, filed August 26, 1993, now abandoned, which was a continuation-in-part of U.S. Serial No. 07/965,662, filed October 23, 1992, now abandoned. This application also claims priority from International Application No. PCT/US93/10168, filed October 22, 1993. The contents of all of the aforementioned application(s) are hereby incorporated by reference.--

In the Claims:

Please cancel claims 21-28 and 46-53.

Please add new claims 56-61 as follows:

56. (New) A method of identifying an inhibitor of selectin-mediated intercellular adhesion which comprises:
- (a) combining a selectin protein with the fusion protein of claim 29, said combination forming a first binding mixture;
 - (b) measuring the amount of binding between the selectin protein and the fusion protein in the first binding mixture;
 - (c) combining a compound with the selectin protein and the fusion protein to form a second binding mixture;
 - (d) measuring the amount of binding in the second binding mixture; and
 - (e) comparing the amount of binding in the first binding mixture with the amount of binding in the second binding mixture;
- wherein the compound is capable of inhibiting selectin-mediated intercellular adhesion when a decrease in the amount of binding of the second binding mixture occurs.
57. (New) A pharmaceutical composition comprising the fusion protein of claim 29 and a pharmaceutically acceptable carrier.

58. (New) A method of treating an inflammatory disease in a subject which comprises administering a therapeutically effective amount of the composition of claim 29 to said subject.

59. (New) The method of claim 58, wherein said inflammatory disease is selected from the group consisting of: arthritis, gout, uveitis, acute respiratory distress syndrome, asthma, emphysema, delayed type hypersensitivity reaction, systemic lupus erythematosus, thermal injury such as burns or frostbite, autoimmune thyroiditis, experimental allergic encephalomyelitis, multiple sclerosis, multiple organ injury syndrome secondary to trauma, diabetes, Reynaud's syndrome, neutrophilic dermatosis, inflammatory bowel disease, Grave's disease, glomerulonephritis, gingivitis, periodontitis, hemolytic uremic syndrome, ulcerative colitis, Crohn's disease, necrotizing enterocolitis, granulocyte transfusion associated syndrome, and cytokine-induced toxicity.

60. (New) A method of inhibiting selectin-mediated binding in a subject comprising administering a therapeutically effective amount of a composition of claim 29 to said subject.

61. (New) The method of claim 60, wherein administration of said composition selectively inhibits P-selectin mediated binding.

REMARKS

Claims 21-28 and 46-53 have been canceled. The cancellation of these claims should in no way be construed as an acquiescence by Applicants to any of the rejections of record involving these claims.

Claims 56-61 have been newly added. Support for new claims 56-61 can be found in the specification and claims as originally filed. Specifically, support for claim 56 can be found, for example, at page 4, lines 13-29. Support for claim 57 can be found, for example, at page 22, line 22 to page 23, line 5. Support for claims 58 and 59 can be found, for example, at page 14, lines 23-25 and page 21, line 34 to page 22, line 10. Support for claims 60 and 61 can be found, for example, at pages 23, lines 24-35 and in Example 4 at pages 32-34.

Applicants submit herewith a **“Version with Markings to Show Changes Made,”** which indicates the specific amendments made to the specification and the claims. No new matter has been added.

Any amendments to and/or cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to expedite prosecution. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

CONCLUSION

It is respectfully submitted that this application is in condition for allowance. If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at (617) 227-7400.

Respectfully submitted,



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Dated: August 21, 2001

Version with Markings to Show Changes Made

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New claims 56-61 have been added as follows:

56. (New) A method of identifying an inhibitor of selectin-mediated intercellular adhesion which comprises:
- (a) combining a selectin protein with the fusion protein of claim 29, said combination forming a first binding mixture;
 - (b) measuring the amount of binding between the selectin protein and the fusion protein in the first binding mixture;
 - (c) combining a compound with the selectin protein and the fusion protein to form a second binding mixture;
 - (d) measuring the amount of binding in the second binding mixture; and
 - (e) comparing the amount of binding in the first binding mixture with the amount of binding in the second binding mixture;
- wherein the compound is capable of inhibiting selectin-mediated intercellular adhesion when a decrease in the amount of binding of the second binding mixture occurs.
57. (New) A pharmaceutical composition comprising the fusion protein of claim 29 and a pharmaceutically acceptable carrier.
58. (New) A method of treating an inflammatory disease in a subject which comprises administering a therapeutically effective amount of the composition of claim 29 to said subject.
59. (New) The method of claim 58, wherein said inflammatory disease is selected from the group consisting of: arthritis, gout, uveitis, acute respiratory distress

syndrome, asthma, emphysema, delayed type hypersensitivity reaction, systemic lupus erythematosus, thermal injury such as burns or frostbite, autoimmune thyroiditis, experimental allergic encephalomyelitis, multiple sclerosis, multiple organ injury syndrome secondary to trauma, diabetes, Reynaud's syndrome, neutrophilic dermatosis, inflammatory bowel disease, Grave's disease, glomerulonephritis, gingivitis, periodontitis, hemolytic uremic syndrome, ulcerative colitis, Crohn's disease, necrotizing enterocolitis, granulocyte transfusion associated syndrome, and cytokine-induced toxicity.

60. (New) A method of inhibiting selectin-mediated binding in a subject comprising administering a therapeutically effective amount of a composition of claim 29 to said subject.

61. (New) The method of claim 60, wherein administration of said composition selectively inhibits P-selectin mediated binding.